Patent Application

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Appl. of | Altman, Peter A. | Art Unit:. 3739 |
| Serial No.: | 10/014,445 | Examiner: Lee S. Cohen |
| Filed: | December 11, 2001 | Atty Docket No.: 23,403-05 |
| Reissue of: | U.S. Patent No. 5,551,427 | |
| For: | Implantable Device for Penetrating and Delivering Agents to Cardiac Tissue | |

SUPPLEMENTAL DECLARATION

As the below-named inventor and applicant for reissue of the above identified U.S. patent, I hereby declare that:

My residence, post office address, and citizenship are as stated immediately below next to my name:

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| Full name of inventor: | Peter A. Altman |
| Residence (City/State): | San Francisco, California |
| Mailing Address: | 5243 California Street<br>San Francisco, CA 94118 |
| Citizenship: | United States |

I believe I am the original, first, and sole inventor of the subject matter described and claimed in U.S. Patent No. 5,551,427, granted September 3, 1996 on U.S. Application Serial No. 387,257 filed February 13, 1995, and for which a reissue patent is sought on the invention entitled Implantable Device for Penetrating and Delivering Agents to Cardiac Tissue, the specification of which has been amended, most recently by an Amendment filed November 4, 2005 (the November 2005 Amendment).

I have reviewed and understand the contents of the above identified specification, including the claims (original claims 1-26 and new claims 27-94) as amended or cancelled by said November 2005 Amendment and any previous amendment.

I acknowledge the duty to disclose information material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56.

With regard to surrender of the patent pursuant to 37 C.F.R. 1.178, I hereby confirm that the original Certificate of U.S. Letters Patent No. 5,551,427 has been surrendered in reissue application Serial Number 09/146,120 for reissue of said U.S. Patent No. 5,551,427.

I believe the original patent to be partly inoperative or invalid by reason of my claiming less than I had a right to claim in the original patent.

In particular, the claims of the original patent are directed to one aspect of the present invention, namely a biocompatible, electrically inactive, implantable device including a means for penetrating cardiac tissue to effect an implantation of the implantable device at a designated site in a heart, to modify electrical action in the cardiac tissue at and proximate the site (claim 21). The claims in the original patent also are directed to a method of locally altering electrical activity in cardiac tissue at a selected site in the region of the heart, including: measuring electrical activity in cardiac tissue, to identify a potential implantation site; and introducing an electrically inactive and biocompatible implantable device into the region of the heart, and at least partially imbedding the implantable device into cardiac tissue at the site to effect an implantation (claim 12).

I believe that the original patent, in particular at column 6 lines 9-16, column 6 lines 61-67 and at column 14 lines 25-39 when considered in conjunction with the drawings and with the remainder of the specification, discloses a further aspect of the invention relating to the use of a structure having a tissue penetrating element for delivering a pharmacological agent, and more particularly an angiogenic agent, to cardiac tissue at and adjacent the penetrating element. The invention further relates to a process for delivering a pharmacological agent and more particularly an angiogenic agent to the heart, by penetrating a delivery device into heart tissue and delivering the agent to the tissue through the delivery device.

Based on my further consideration of the claims of the original patent, and consultation with my patent attorneys and others concerning the patented claims, I now believe that the original patent claims do not sufficiently claim the aforementioned aspects of the invention. The aforementioned reissue application serial number 09/146,120, issued December 11, 2001 as Reissue Patent number Re. 37,463, addresses this error. New claims 27-94 of the present reissue application, as amended or cancelled by the November 2005 Amendment and any previous amendment, are intended to further address this error.

Every error in the patent which has been corrected in the present reissue application as amended, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Wherefore, I hereby petition for a reissue of U.S. Patent No. 5,551,427 under 35 U.S. Code Section 251 in accordance with the aforementioned specification and claims, and I hereby subscribe my name to said specification and claims and to this declaration, and petition.

Date: 31 January 2006

Peter A. Altman

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